

**IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF DELAWARE**

BIOGEN INTERNATIONAL GMBH  
and BIOGEN MA INC.,

Plaintiffs,

v.

AMNEAL PHARMACEUTICALS LLC,  
et al.,

Defendants.

Civil Action No. 17-823-LPS  
(Consolidated)

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**DEFENDANTS' NOTICE PURSUANT TO 35 U.S.C. § 282**

Pursuant to 35 U.S.C. § 282, Hetero USA Inc., Hetero Labs Limited Unit-III, and Hetero Labs Limited, MSN Laboratories Private Ltd. and MSN Pharmaceuticals Inc., Princeton Pharmaceutical Inc., Sandoz Inc., Sawai USA, Inc. and Sawai Pharmaceutical Co., Ltd., Shilpa Medicare Limited, Zydus Pharmaceuticals (USA) Inc., and Aurobindo Pharma U.S.A., Inc. and Aurobindo Pharma USA LLC (collectively, "Defendants") hereby give notice to Biogen International GmbH and Biogen MA Inc. (collectively "Plaintiffs") that Defendants may rely on one or more of the identified prior art (including any file histories corresponding to any identified patents and their priority applications) to show that claims 1-4, 6, 8-13, 15 and 16 of United States Patent No. 8,399,514 ("the '514 patent") are invalid and/or to show the state of the pertinent art:

**I. PATENTS AND PATENT PUBLICATIONS**

Country	Number	Date Issued/Published	Inventor	DTX
United States	2003/0018072	Jan. 23, 2003	Joshi et al.	DTX-338
United States	2009/034790	Dec. 10, 2009	Nilsson et al.	DTX-339

Country	Number	Date Issued/Published	Inventor	DTX
United States	6,509,376	Jan. 21, 2003	Joshi et al.	DTX-340
United States	7,320,999	Jan. 22, 2008	Joshi et al.	DTX341
United States	7,619,001	Nov. 17, 2009	Joshi et al.	DTX-182
United States	8,399,514	Mar. 19, 2013	Lukashev et al.	DTX-001
International	2006/037342 A2	April 13, 2006	Nilsson, Henrik	DTX-324
International	2007/042034 A1	April 19, 2007	Nilsson, Henrik	DTX-325

## II. OTHER PUBLICATIONS

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Antel, J., <i>Oligodendrocyte/myelin injury and repair as a function of the central nervous system environment</i> , 108 J. Clin Neurol Neurosurg. 245-249 (Mar. 2006) (DTX-408)
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Boutros, T., et al., <i>Interferon-<math>\beta</math> is a Potent Promoter of Nerve Growth Factor Production by Astrocytes</i> , 69 J Neurochemistry 939-946 (1997) (DTX-409)
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Description
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Calabresi, P.A., <i>Diagnosis and Management of Multiple Sclerosis</i> , 70 American Family Physician, 1935-1944, 1935 (Nov. 15, 2004) (DTX-382)
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Freedman, M.S., <i>Disease-modifying drugs for multiple sclerosis: current and future aspects</i> , 7 Expert Opin. Pharmacother. 7 Suppl 1:S1-9 (2006) (DTX-417)
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Schimrigk S., et al., <i>Oral Fumaric Acid Esters (FAE) in Relapsing-Relmitting Multiple Sclerosis (RRMS). A Short Term, Open, Clinical, Immunological and Magnetic Resonance Imaging (MRI) Controlled Phase II Trial</i> (Abstract 144), J. Neurology, 246(1):36 (1999) (DTX-336)
Schimrigk S., et al., Poster, <i>A prospective, open-label, phase II study of oral fumarate therapy for the treatment of relapsing- remitting multiple sclerosis</i> , available at <a href="http://www.fumapharm.ch:80/pdf /BG- 12_Schimrigk_Poster_Final.pdf">http://www.fumapharm.ch:80/pdf /BG- 12_Schimrigk_Poster_Final.pdf</a> (Oct. 21, 2004) (DTX-337)
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Defendants further disclose that the asserted claims of the '514 patent are invalid for improper inventorship and derivation from communications with reviewers at the FDA regarding the design of Biogen's Phase III clinical trials.

Defendants affirmatively state that they have already provided notice/will provide notice to Plaintiffs of the identity of certain publications and patents within the ambit of 35 U.S.C. § 282, through the pleadings, invalidity contentions, correspondence and other documents in this case, including, but not limited to, expert witness reports and materials cited therein, expert witness testimony, Defendants' prior responses to interrogatories, and the Joint Pretrial Order. Defendants expressly incorporate herein by reference all of those documents, and the publications and patents within the ambit of § 282 previously cited therein, to the extent not listed above. Additionally, to

the extent not listed above, Defendants incorporate by reference each document listed on the face of or included in the prosecution history of the '514 patent. Defendants also incorporate by reference each of the expert reports (including reply reports) of Dr. Gary A. Stobbe, Dr. V. Wee Yong, and Dr. John William Lindsey, and any prior art cited therein, in Civil Action No. 17-823-LPS.

Dated: November 08, 2019

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